

language.

Claims 1-12 and 31-32 are rejected under 35 USC 103(a) as being unpatentable over Chang (US Pat 6,722,002).

The Examiner objects that Chang teaches a brazing filler material comprising laminated foil layers. Then the Examiner finds that, "Chang further teaches a brazed component assembly comprising a 316 stainless steel metal part bonded to a composite filler material comprising two outer foil layers of nickel and an inner foil core layer of titanium (col. 6, ln. 52-57). Chang also teaches that titanium metal parts can be bonded to other metal parts by employing the brazing filler material to form a composite assembly." This can only be correct if roll bonding is somehow construed to be brazing. This understanding is critical to understanding the invention of Applicant. As is well known, a brazed component is potentially suitable for use in living tissue, while roll bonded components that contain nickel never are implantable because roll bonded components have a distinct nickel foil layer that is poisonous to living tissue. Brazing of course leaves no nickel available to poison living tissue.

Applicant examines these statements separately. Chang teaches the brazing filler material "...can be roll bonded to suitable alloy strips to form self-brazing materials. Typical example is to roll bond 0.010" thick Ni/Ti/Ni strips to a 0.040" thick 316 stainless steel. The self braze strip is further cold rolled to 0.015" thick which has 20% thickness (0.003" thick) of brazing layers.

The resulting five layer composite, or other variations, can be placed between two sheets of 0.020" thick Beta-21 Ti alloys and placed in a vacuum furnace for brazing." [Chang col 6, lines 52-60]

First, the teaching is so poorly written that it is readily subject to misinterpretation, consider for example how Chang mysteriously obtains a 5-layer composite after adding a 3-layer "Ni/Ti/Ni strips" to "a 0.040" thick 316 stainless steel." It is nonsensical. One cannot correctly conclude that Chang teaches brazing unless the very critical teaching of Chang is changed by inserting "bonding" in place of Chang's "roll bonding." Chang teaches that the composite

can be roll bonded to form strips suitable for self-brazing materials. Chang teaches that the Ni/Ti/Ni strip is roll bonded to a 0.040" thick 316 stainless steel. It is well understood that two critical terms of art, "bonding" and "filler" refer to brazed materials and not to roll bonded materials. [Bonding refers to welding, brazing, or soldering, while filler is the metal added in making a brazed, soldered, or welded joint.] To conclude that Chang teaches bonding, by changing the term "roll bonding" to "bonding" confuses a useless and poisonous material with an implantable material.

Chang next teaches that "[t]he resulting five layer composite, or other variations, can be placed between two sheets of 0.020" thick Beta-21 Ti alloys and placed in a vacuum furnace for brazing." This means that the 316 stainless steel layers are each next to the two Beta-21 Ti alloy. The Ni/Ti/Ni is sandwiched between the two 316 stainless steel outer layers of the 5-layer composite. Chang does not demonstrate an understanding of nor demonstrate any teaching of bonding Ti to stainless steel with a filler material. How anyone could take Chang's teaching and then practice brazing of Ti to stainless steel as taught by Applicant remains a mystery. The declaration of Jiang attached hereto explains that Chang does not teach the use of a brazing foil to braze stainless steel to titanium.

The teaching of Chang cited at col 5, lines 40-56 is directed to forming by roll bonding a brazing strip or foil such as that discussed above and comprising Ni/Ti/Ni. At line 42, Chang states that the resulting brazing alloy according to his invention is useful for brazing Ti, Ni or Fe based alloys. As discussed previously, Chang teaches bonding stainless to stainless with the brazing foil. He teaches bonding Ti to Ti with a sandwich that is wrapped in stainless as the 5-layer composite.

The Examiner admits that Chang does not teach a component assembly comprising a stainless steel part bonded to a titanium part via a filler layer comprising nickel and titanium foils. [Office action page 3 last para.] However contrary to the Examiner's conclusion, Chang does not teach bonding a titanium part with the filler comprising nickel and titanium layers. As discussed previously, according to the teachings of Chang, the Ni/Ti/Ni is bonding [bonding is the correct

term since Chang teaches bonding by brazing of the two stainless parts to form the 5-layer composite] the stainless steel to itself. Chang does not teach bonding the Beta-21 alloy strip as found by the Examiner.

Limitation to Use in Living Tissue

It is common knowledge that Ni is not implantable in living tissue. A declaration to this effect is included herein by the inventor. It is also common knowledge that free nickel is not available post-brazing; in start contrast to the product of roll-bonding. The inventor's declaration also puts this fact in the record.

This statement of intended use in living tissue is argued to be a limitation since it defines the very invention, the need to eliminate free nickel for example. Without this limitation of the component assembly to implantable materials and process which yield an implantable device, the claim would have no meaning. Without the preamble limitation to "use in living tissue" there is no limitation to materials selections, for example. This limitation is not a mere extolling of benefits or features of the claimed invention. Reliance on the preamble distinguishes the claimed invention from the prior art and transforms the preamble into a claim limitation. Deletion of the preamble affects the structure of the claimed invention leading to the conclusion that the limitation to use in living tissue is properly considered as a limitation.

Claim 13 is rejected under 35 USC 103(a) as being unpatentable over Chang in view of Cusano (US Pat 3,994,430).

Applicant elects not to address this rejection and to rely on Claim 13 being allowable as a further limitation on an allowable independent claim.

CLAIMS

The claims are amended herein.

Claim 1 is amended to indicate that the component article contains no free nickel, which would be poisonous to living tissue.

Claim 32 is amended with the addition of terms to clarify that the claim is

drawn to a future treatment.

In view of the foregoing, it is respectfully submitted that the pending claims 1-13; 31 and 32 are allowable as amended and in the present application. Reexamination and allowance are respectfully requested.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California area telephone number (661) 702-6814 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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Date



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